GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:282
ANSWERED ON:03.02.2017
Regulatory Reforms for Medical Device Sector
Joshi Shri Pralhad Venkatesh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government proposes to bring regulatory reforms for the medical device sector, keeping in view of the objectives under "Make in India";

(b) if so, the details thereof;

(c) the extent to which such move would help reducing India"s import dependence; and

(d) the details thereof?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(FAGGAN SINGH FULASTE)
(a) & (b): The Ministry of Health and Family Welfare had, with a view to providing a transparent, predictable and objective regulatory framework that will ensure quality, safety and performance of the regulated medical devices imported or manufactured for sale in the country and for promoting the ease of doing business, e-gazetted draft Medical Device Rules, 2016 on 17.10.2016 for comments and suggestions of the public. After examination of comments and suggestions received, the rules have since been finalised. Separately, several initiatives including duty rationalization for medical devices have been taken by the Government to promote Make in India.
(c) & (d): The Medical Device Rules, based broadly on International guidelines coupled with other initiatives of the Government, is expected to provide a conducive environment for the growth of medical devices industry in the country.
â€¦â€¦â€¦